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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,407	02/06/2002	R Rex Denton	MWH-0006US	1146
25106	7590	02/13/2004	EXAMINER	
GENAISSANCE PHARMACEUTICALS			QIAN, CELINE X	
5 SCIENCE PARK			ART UNIT	
NEW HAVEN, CT 06511			PAPER NUMBER	
			1636	
DATE MAILED: 02/13/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/049,407

Applicant(s)

DENTON ET AL

Examiner

Celine X Qian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-26 are pending in the application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 6 and 7, drawn to an isolated polynucleotide comprising a first nucleotide sequence being a polymorphic variant of HTR1A gene, a fragment thereof, and a second nucleotide sequence being a complementary sequence to the first sequence.

Group II, claim(s) 4, 5, 8 and 9, drawn to a recombinant organism transformed with the polynucleotide of claim 1.

Group III, claim 10, drawn to an isolated polypeptide comprising an amino acid sequence which is a polymorphic variant of the HTR1A protein or a fragment.

Group IV, claim 11, drawn to an antibody specific for and immunoreactive with the polypeptide comprising an amino acid sequence which is a polymorphic variant of the HTR1A protein or a fragment.

Group V, claim 12, drawn to a method for screening drugs targeting the isolated polypeptide comprising an amino acid sequence which is a polymorphic variant of the HTR1A protein or a fragment, said method comprising contacting the HTR1A polymorphic variant with a candidate agent and assaying for binding activity.

Group VI, claims 13-16, drawn to a composition comprising at least one genotyping oligonucleotide for detecting a polymorphism in the HTR1A gene at a polymorphic site selected from PS1, PS5 and PS6.

Group VII, claims 17-20, drawn to a method for genotyping HTR1A gene of an individual by screening for polymorphic sites within the two copies of the HTR1A gene.

Group VIII, claim 21, drawn to a method for predicting a haplotype pair for HTR1A gene of an individual.

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Group IX, claims 22-24, drawn to method for identifying an association between a trait and a genotype of the HTR1A gene.

Group X, claim 25, drawn to a computer system for storing and analyzing polymorphism data for the HTR1A gene.

Group XI, claim 26, drawn to a genome anthology for the HTR1A gene.

PCT Rule 13.2 requires that unity of invention exists only when the shared same of corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-XI do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The “special technical feature” of Group I is an isolated nucleic acid comprising a first nucleic acid sequence being a polymorphic variant of HTR1A or a fragment, and a second nucleic acid sequence complementary to the first nucleic acid sequence, which is shown by Kawanishi et al (1998) to lack novelty or inventive step. Kawanishi et al. disclose a number of fragments and complementary sequences of HTR1A gene (see table 1). Therefore, the special technical feature of group I does not make a contribution over the prior art.

The remaining groups are all directed to composition and methods related to the HTR1A gene or protein. However, each group has a different special technical feature not shared by the remaining groups. For example, the special technical feature of Group II is recombinant organism transformed with HTR1A variants, which is not share by the remaining group. The special technical feature of Group III is the polypeptide encoding HTR1A with polymorphic site, which is not shared by the remaining groups. The special technical feature of Group IV is the antibody for the polypeptide encoding HTR1A with polymorphic site, which is not shared by remaining groups. Groups V, VII-IX are drawn to different methods that requires different

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starting materials and modes of operation. Groups VI, X and XI are drawn to oligonucleotides, computer system and isogenes of HTR1A, each of which has special technical feature not shared by the other. Therefore, the invention of Groups I-XI lacks unity under PCT Rule 13.2.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine Qian, Ph.D.

Anne-Marie Falk
ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER